REMARKS

These papers are submitted in response to the Office Action dated May 12, 2006. Applicants request entry of the Amendment and Response and reconsideration of the rejection of the claims in view of the following remarks.

With entry of this amendment, Claims 1-15 and 17 are canceled without prejudice or disclaimer, in favor of amended claim 16 and new claims 18 - 29. Support for new claims 18-29 is found throughout the specification, including for example, at paragraph [0033]-[0038], and [0046]-[0052] (page 6, line 18 to page 7, line 30; and page 9, line 5 and page 10, line 23).

Priority

Acceptance of priority to the European application under 35 USC § 119(b) is noted.

35 USC § 102

1. Gimet

Claims 1-9 and 11-14 are rejected as being allegedly anticipated under §102(b) by Gimet et al., US 5,601,843. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

2. Chemburkar

Claims 1-9 are rejected as being allegedly anticipated under §102(b) by Chemburkar et al., US 5,213,807. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

3. Ouali

Claims 1-6 and 8-14 are rejected as being allegedly anticipated under §102(b) by Ouali et al., US 6,183,779. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

4. Sherman

Claims 1-9 and 11 are rejected as being allegedly anticipated under §102(e) by Sherman et al., US 6,656,503. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

5. Woolfe

Claims 1-6 and 9-11 are rejected as being allegedly anticipated under §102(e) by Woolfe et al., US 2002/0054908. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

35 USC § 103

Claims 12-14 are rejected as allegedly being obvious over Woolfe et al., US 2002/0054908. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

Claims 12-14 are also rejected as allegedly being obvious over Chemburkar or Sherman in view of Ouali. Applicants respectfully disagree and traverse this rejection. This rejection is rendered moot by cancellation of claims 1-15.

Claims 16-17 are rejected as allegedly being obvious over Woolfe et al., US 2002/0054908 in view of Ouali.

To support a rejection under 35 U.S.C. section 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In particular, a prima facie case of obviousness requires the references when combined must teach or suggest all of the claim limitations. Applicants submit that all of these requirements have not been met.

Independent claim 16 is directed to an extended-release first portion of NSAIDs and an immediate release second portion made of a stabilised gastroprotective prostaglandin, wherein the extended release first portion and the immediate release second portion are encapsulated within a capsule made of hydroxyl-propyl-methyl-cellulose (HPMC) polymer.

In contrast the cited references, --Gimet, --Woolfe, or --Chemburkar or Sherman in view of Ouali do not teach extended release formulations, in particular compounding an NSAID with one or more retardants for extended release. Gimet, Woolfe, Chemburkar, Sherman and Ouali all rely on enteric coatings, which is a form of delayed release. The enteric coating on the cores or granules of the references delays absorption, targeting release in the intestine rather than the stomach. Once the enteric coating is penetrated, the cores and granules are rapidly disintegrated.

In contrast, the claimed pharmaceutical compositions require a dual-release solid pharmaceutical composition wherein an extended-release first region comprising at least one NSAID and a retardant material, is combined with an immediate release second region comprising a stabilized gastroprotective prostaglandin –both portions encapsulated within an HPMC capsule. As argued above, the cited references do not teach compounding retardant materials with an NSAID for form an extended-release portion, and further do not propose combining an extended-release NSAID with an immediate release prostaglandin. Furthermore, the nature of extended-release is sufficiently different from simple delayed release and enteric coated NSAIDS. The extended-release NSAID with retardant as claimed is released gradually throughout the gastrointestinal system starting from an oral administration in order to obtain release of the NSAID in the stomach and the intestine. In contrast, delayed release formulations (.e.g, enteric coatings) are used with the purpose of isolating complete release of the encapsulated compound to the small intestines for the purpose of avoiding NSAID contact with the stomach and possible stomach problems. Therefore, the teachings of the cited references for use of delayed release, including enteric coatings is not sufficient to reach the claimed pharmaceutical composition.

In addition, use of a gelatin capsule instead of an HPMC capsule are not acceptable equivalents for use in encapsulating the claimed two portion pharmaceutical composition. In particular, it has been found that an unexpected increase in stability of the pharmaceutical composition in the HPMC capsules. Applicants present a Declaration under 37 C.F.R. § 1.132 by Dr. Michel Franz providing evidence of the discovery that HPMC capsules provide a clear advantage over gelatin capsules.

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: November 10, 2006

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